Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Efficacy of Lotion Containing Black Rice Bran (Oryza sativa L. indica) Extract with Placebo as Skin Brightening Agent with in Healthy Asian Women

Protocol summary

Study aim
This research is about black rice bran extract which is formulated into lotions which have great potential as a skin care product to brighten the skin.
Design
Parallel group trial with double blinded application of lotion
Settings and conduct
Each participants are applying lotion A in left elbow and lotion B right elbow twice a day (every morning and evening) for 14 days. Both participants and researchers are blinded
Participants/Inclusion and exclusion criteria
woman, Asian race, age range 18-25 years; healthy skin condition; has no history of allergies; not pregnant or breastfeeding; has no chronic medical history,, does not have tattoos, scars or burns; not currently using therapies such as anti-inflammatory, corticosteroids, hormonal contraceptives, or lasers; and do not smoke, do not drink alcohol and do not use drugs, do not orally consume the test substance (black rice bran extract) and skin brightening agent.
Intervention groups
Lotions containing extract and placebo were applied twice a day in both elbow
Main outcome variables
The skin melanin after application of lotions were measured with mexameter

General information

Reason for update
Acronym
BRBCT
IRCT registration information
IRCT registration number: **IRCT20210412050942N1**
Registration date: **2021-05-01, 1400/02/11**
Registration timing: **retrospective**

Last update: **2021-05-01, 1400/02/11**
Update count: **0**
Registration date
2021-05-01, 1400/02/11

Registrant information
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Afifah Vardhani
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-01, 1398/10/11
Expected recruitment end date
2020-03-23, 1399/01/04
Actual recruitment start date
2020-01-01, 1398/10/11
Actual recruitment end date
2020-02-23, 1398/12/04
Trial completion date
2020-03-12, 1398/12/22

Scientific title
Comparison of the Efficacy of Lotion Containing Black Rice Bran (Oryza sativa L. indica) Extract with Placebo as Skin Brightening Agent with in Healthy Asian Women

Public title

Efficacy of Lotion Containing Black Rice Bran (Oryza sativa L. indica) Extract as Skin Brightening Agent, a Clinical

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

healthy skin condition; Asian race

Exclusion criteria:

history of allergies; pregnant or breastfeeding; chronic medical history, have tattoos, scars or burns; currently using therapies such as anti-inflammatory, corticosteroids, hormonal contraceptives, or lasers; smoke, drink alcohol and use drugs, orally consume the test substance (black rice bran extract), apply and consume skin brightening agent topically or orally

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
one sample is lotion containing extract, another is placebo lotion
Actual sample size reached: **34**
More than 1 sample in each individual
Actual sample size in each individual: **2**
one sample is lotion containing extract, another is placebo lotion

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be given 2 types of lotions to use on right and left elbows, which are applied evenly until they are absorbed. The lotions given have been coded, namely code A-right and code-B-left. This study lasted for 2 weeks (14 days). Every day, participants have to use the lotion for 14 days, twice a day in the morning and evening, each of approximately 1 gram by first washing participants' hands which will be smeared with the lotion and wiped dry. Participants are also asked to rub code A lotion on the back of participants' right hand using the finger of participants' left hand, and apply code B lotion to the back of participants' left hand using the finger of participants' right hand. This is done to prevent lotion A and lotion from mixing. Apply using participants' fingers until all of the lotion is evenly spread and absorbed well. Participants' are prohibited from washing hands at least 1 hour after using the product. Day 14, the use of the lotion is stopped and the researchers will re-check some parameters of participants' skin's brightness level with a Mexameter tool.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee, Faculty of Medicine, University of Indonesia

Street address

Salemba Raya No 6

City

Jakarta

Postal code

10430

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

19-10-1170

Health conditions studied

1

Description of health condition studied

Healthy skin condition

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Melanin index

Timepoint

2 weeks after intervention

Method of measurement

Measure skin melanin index with mexameter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one lotion containing black rice bran extract 10% is applied in one side of volunteer's volar. each application of lotion is 0,5 gram, applied in diameter 5 centimeters. Lotion is applied twice a day (every morning and evening after shower) for 14 days. the excipients of lotions are demineralized aqua, olive oil, vaseline album, dimethicone. Cetyl alcohol, isopropyl myristate, span 80, propylparaben, BHT, tween 80, methylparaben, and glycerin. They are manufactured by Brataco (Indonesia)

Category
Treatment - Other

2

Description
Control group: one placebo lotion were applied in the other side of volunteer's volar. each application of lotion is 0,5 gram, applied in diameter 5 centimeters. Lotion is applied twice a day (every morning and evening after shower) for 14 days. the excipients of lotions are demineralized aqua, olive oil, vaseline album, dimethicone. Cetyl alcohol, isopropyl myristate, span 80, propylparaben, BHT, tween 80, methylparaben, glycerin and colorant. They are manufactured by Brataco (Indonesia)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Pharmacy, University of Indonesia

Full name of responsible person
dr. Afifah Kusuma Vardhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Integrated Laboratory and Research Center, University of Indonesia.

Full name of responsible person
Dede Djuhana, Ph.D

Street address
Lingkar Kampus UI

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16424

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+62 622 17270152

Email
drpm@ui.ac.id

Web page address
https://research.ui.ac.id/research/

Grant name
QQ Grant

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Integrated Laboratory and Research Center, University of Indonesia.

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Indonesia

Full name of responsible person
Afifah Kusuma Vardhani

Position
Post graduate

Latest degree
Master

Other areas of specialty/work
Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available